REMARKS

Claims 1, 11, 17-19, and 22-23 have been canceled without prejudice or disclaimer. Applicants reserve the right to pursue the subject matter encompassed by all canceled claims in one or more continuing applications. Claim 45 has been amended to replace the word "sequence" with "residues." Claims 43, 70, 88, 114 and 115 have been amended to replace "CRCGCL" with "cytokine receptor common gamma chain like." Support for this amendment can be found in the title of the specification. No new matter has been entered. Upon entry of the present amendments, claims 25-120 will be pending.

I. Advisory Information

Applicants respectfully submit that the instant claims can encompass, but are not limited to, antibody fragments that specifically bind the proteins of the invention.

II. Specification

As suggested by the Examiner in section 4 of Paper No. 12042003, Applicants have amended the title of the instant application to more clearly indicate the invention to which the claims are directed. The title now reads "Antibodies to Cytokine Receptor Common Gamma Chain Like."

III. Claim Objections

On page 5, section 5 of Paper No. 12042003, claims 43, 70, 88 and 114 are objected to for reciting "CRCGCL." Applicants have amended claims 43, 70, 88 and 114 to replace "CRCGCL" with "cytokine receptor common gamma chain like" as requested by the Examiner. Claim 115 has also been amended in this manner. As such, Applicants respectfully request that this objection be reconsidered and withdrawn.

IV. Claim Rejections under 35 USC §112, second paragraph

In section 6 on page 4 of Paper No. 12042003, claims 25-120 are rejected as being allegedly indefinite. Specifically, the Examiner states,

> The specification does not define what the term "specifically binds" means, and discusses on pages 72-75 that the binding of antibodies can exclude or include binding to related proteins of various percent

> identities. The term "specifically binds" is considered indefinite, since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

See lines 5-9 of section 6 on page 4 of Paper No. 12042003. Applicants respectfully disagree and traverse this rejection.

As a threshold matter, Applicants point out that the M.P.E.P. instructs that requirements for clarity and precision must be balanced with limitations of the language and science. *See*, M.P.E.P. § 2173.05(a). And, "[i]f the claims, read in light of the specification, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, the statute (35 USC 112, second paragraph) demands no more." M.P.E.P. 2173.05(a) *citing*, *Shatterproof Glass Corp. v. Libby Owens Ford Co.*, 758 F.2d 613, 225 USPQ 634 (Fed. Cir. 1985); *and Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81 (Fed. Cir. 1986).

The Federal Circuit has repeatedly recognized that claims may use language that those of skill in the art understand without the need for explicit, detailed definitions in the specification. In *W.L. Gore and Associates, Inc v. Garlock , Inc* (721 F.2d 1540, 1556-1558 (Fed. Cir. 1983)), claims were held definite because the evidence showed that persons of ordinary skill in the art understood their meaning despite the fact that the specification did not disclose precise definitions of certain terms of art. See also, *Orthokinetics, Inc. v. Safety Travel Chairs, Inc., 806 F.2d 1565, 1575-76, (Fed. Cir. 1986)* (claims using the phrase "so dimensioned" were held definite even though the specification did not provide exact dimensions because one of skill in the art "realized that the dimensions could be easily obtained") and *Personalized Media Communications, LLC v. International Trade Comm'n, 161 F.3d 696, 704-06, (Fed. Cir. 1998)* (claims held as definite, for example, where the written description disclosed only a black box for an electrical component--"digital detector"--because the definition provided in the written description, "a device that 'acts to detect the digital signal information' in another stream of information," was sufficient in light of the "well-known meaning" of the term "detector" to "those of skill in the electrical arts.").

Nor does the fact that a term is "relative" render a claim indefinite. Section 2173.05 of the M.P.E.P (8th Edition, Revision 1) states that:

> The fact that claim language, including terms of degree, may not be precise, does not automatically render the claim indefinite under 35 USC 112, second paragraph. *Seattle Box Co., v. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 221 USPQ 568 (Fed. Cir. 1984). Acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification.

Section 2173.05 of the M.P.E.P further states that if the specification does not disclose a standard for measuring the term of degree, "a determination is made as to whether one of ordinary skill in the art, in view of the prior art and the status of the art, would be nevertheless reasonably apprised of the scope of the invention."

Applicants assert that the phrase "specifically binds" is a term of art routinely used, recognized, and understood by those of ordinary skill in the antibody arts. As evidence thereof, Applicants submit herewith a Declaration under 37 C.F.R. §1.132 by Dr. Viktor Roschke. As exemplified by Dr. Roschke's curriculum vitae (attached as Exhibit 1 to the Declaration), Dr. Roschke is highly experienced in, and familiar with, the antibody research field. Dr. Roschke's Declaration clearly indicates that on or before March 19, 1998, the earliest effective filing date of the instant application, practitioners who routinely used antibodies in research would have understood the meaning of the term "specifically binds". *See, e.g.,* Declaration of Vicktor Roschke, page 4, section III(A). In particular, Dr. Roschke explains in the Declaration that on or before March 19, 1998, an antibody that "specifically bound" a protein was understood to be an antibody that under empirically optimized antibody binding conditions: a) was useful in biological assays, diagnostic assays, or therapeutic protocols because of its ability to discriminate between the target protein and non-target proteins; b) bound the protein against which it was raised/screened with significantly higher affinity than it bound other proteins (*i.e.*, paralogues and unrelated proteins); and, c) might also bind fragments of the protein and/or variants of the protein against which it was raised/screened (*e.g.,* post-translationally processed forms of the protein, orthologous proteins, and proteins encoded by alternative alleles or alternatively spliced transcripts). *See*, Declaration of Viktor Roschke, pages 9-10, section V(A).

Thus, Applicants submit that this Declaration and the exhibits submitted therewith (*i.e.*, Exhibits 1-6), fully support Applicants' arguments that the case law, in addition to the skilled artisan, recognize the metes and bounds of the term "specifically binds" as used

in the instant claims. Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the rejection of claims 25-120 under 35 USC § 112, second paragraph for alleged indefiniteness.

V. Claims rejections under 35 USC §112, first paragraph

A. Claims 45, 50-53, 90 and 94-97

In section 7.1 starting on page 5 of Paper No. 12042003, claims 45, 50-53, 90 and 94-97 are rejected for allegedly lacking written description in the specification. Specifically, the Examiner states,

> [T]he claims as written include antibodies to polypeptides comprising fragments and homologues, encompass antibodies to polypeptides that vary substantially in length and also in amino acid composition. For example, claim 45, sections (e) and (f) are drawn to antibodies obtained from an animal that has been immunized with a protein that ***comprises*** the amino acid sequence of at least 30 or 50 contiguous amino acid residues of SEQ ID NO:2, and such a protein can have a significantly different amino acid sequence from that of the protein of SEQ ID NO:2, and therefore may generate antibodies that would not bind to the protein of SEQ ID NO:2.

See lines 7-14 on page 5 of Paper No. 12042003. Applicants respectfully disagree and traverse this rejection.

The test for the written description requirement is whether one of ordinary skill in the art could reasonably conclude that the inventor has possession of the claimed invention in the specification as filed. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991); M.P.E.P. § 2163.02. Further, the Federal Circuit recently re-emphasized the well-settled principle of law that "[t]he written description requirement does not require the applicant 'to describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [they] invented what is claimed,'" *Union Oil Co. v. Atlantic Richfield Co.*, 208 F.3d 989, 54 U.S.P.Q.2d 1227 (Fed. Cir. 2000). The court emphasized the importance of what the person of ordinary skill in the art would understand from reading the specification, *rather than whether the specific embodiments had been explicitly described or exemplified.* Indeed, as the court noted, "the issue is whether one of skill in the art could derive the claimed ranges from the patent's disclosure." *Unocal*, 208 F.3d at 1001 (emphasis added).

See also, Nelson v. Bowler, 1 USPQ2d 2076, 2078-2079 (Bd. Pat. App. & Int'f 1986) ("[W]here the claims involved are drawn to specific compounds, it is well settled that it is not necessary for a party to expressly name the compounds to comply with the written description requirement ... The issue is whether the Nelson specifications convey clearly to those skilled in the art that Nelson invented the compounds at issue ...).

In an analysis of written description under 35 U.S.C. § 112, first paragraph, the Examiner bears the initial burden of presenting a *prima facie* case of unpatentability. This burden is only discharged if the Examiner can present evidence or reasons why one of ordinary skill in the art would not reasonably conclude that Applicants possessed the subject matter as of the priority date of the present application. *In re Wertheim*, 541 F.2d 257, 262, 191 USPQ2d 90, 96 (C.C.P.A. 1976); M.P.E.P. § 2163.04. In the instant case, the Examiner has not met this burden.

Applicants recognize that the Examiner is in part relying on language regarding a "representative number" of a claimed genus set forth in *Regents of the University of California v. Eli Lilly & Co.*, (119 F.3d 1559, 1569, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997)) and incorporated into the Guidelines for Examination of Patent Applications Under the 35 U.S.C. § 112, ¶ 1 "Written Description" Requirement ("Guidelines"), when reciting the procedures followed in analyzing whether the description requirement for each of the claims at issue is satisfied. The central issue in *Eli Lilly* involved claims to mammalian cDNAs encoding insulin, which were supported in the specification only by the nucleotide sequence for the rat insulin gene. The Federal Circuit found the claims lacking in written description because the claims defined only a result or function. The court held that a result or function will satisfy the written description requirement *only if* correlated to a description of structural features of the claimed invention. According to the court, a sufficient written description must allow the skilled artisan to "visualize or recognize the identity of the members of the genus." *Id.*

Unlike the situation in *Eli Lilly*, the presently rejected claims do not recite polypeptides merely by result or function. Applicants submit that the specification does, indeed, provided adequate written description to enable one of skill in the art to immediately envision the identity of the members of the genus. Applicants submit that claims 45, 50-53, 90 and 94-97 are fully disclosed in the instant specification, for example, at page 64, paragraph 132 through paragraph 140 on page 68. It is well-established that a

"gene is a chemical compound, albeit a complex one". *Amgen, Inc. v. Chugai Pharamceutical Co., LTD.*, 927 F.2d 1200, 1206 (Fed. Cir. 1991). Thus, the instant claims directed to antibodies that specifically bind specified fragments of the amino acid sequence of the disclosed SEQ ID NO:2 (or of the polypeptide encoded by the cDNA of the claimed deposit), are chemical claims involving generic chemical formulas. As stated by Judge Lourie in *Eli Lilly*, *supra*, "In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass." All of the objectives met by a generic chemical formula are similarly met by the explicit description in the instant specification of both a polynucleotide and polypeptide sequence (*i.e.* SEQ ID NOs:1 and 2).

Furthermore, claim 45 as amended, recites the limitation "wherein said antibody or fragment thereof specifically binds to said amino acid residues." A similar recitation is found in claim 90. Thus, the Examiner's concerns that the rejected claims would encompass antibodies that would not bind to the protein of SEQ ID NO: 2 are unfounded. That is, the instant claims clearly distinguish the boundaries of the claimed genus and identify all of the members of said genus. Accordingly, one skilled in the art would reasonably conclude that Applicants had possession of the claimed antibodies encompassed by the rejected claims, upon reading the present application as filed.

In view of these remarks, Applicants submit that claims 45, 50-53, 90 and 94-97 are fully supported by a written description in the specification as filed. Therefore, Applicants respectfully request that this rejection be reconsidered and withdrawn.

B. Claims 71-114

In section 7.2 starting on page 6 of Paper No. 12042003, claims 71-114 are rejected for allegedly lacking enablement in the specification. Specifically, the Examiner states,

> Applicants referral to the deposit of cDNA clone HTAEK53 as ATCC number 209641 on page 3 of the specification is an insufficient assurance that all of the conditions of 37 CFR section 1.801 through 1.809 have been met.

See lines 1-4 on page 7 of Paper No. 12042003. In the last three lines of section 7.2 on page 7, it is further stated that "amendment of the specification to recite the date of the

deposit, the complete name and address of the depository, and the accession number of the deposited cell line is requested."

Preliminarily, Applicants submit that the specification as filed clearly discloses the date of the deposit, the complete name and address of the depository, and the accession number of the deposited cell line. Specifically, paragraph number 45 on page 14 of the specification recites,

> In the present invention, the full length CRCGCL sequence identified as SEQ ID NO:1 was generated by overlapping sequences of the deposited clone (contig analysis). A representative clone containing all or most of the sequence for SEQ ID NO:1 was deposited with the American Type Culture Collection ("ATCC") on February 25, 1998, and given ATCC Deposit Number 209641. A second clone was also deposited with the ATCC on March 23, 1998, and was given the ATCC Deposit Number 209691. The ATCC is located at 10801 University Boulevard, Manassas, VA 20110-2209, USA. The ATCC deposit was made pursuant to the terms of the Budapest Treaty on the international recognition of the deposit of microorganisms for purposes of patent procedure.

In addition, Applicants' representative hereby gives the following assurance by signature below:

Human Genome Sciences, Inc., the assignee of the present application, has deposited biological material under the terms of the Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure with the following International Depository Authority: American Type Culture Collection (ATCC), 10801 University Boulevard, Manassas, Virginia 20110-2209 (present address). The deposit was made on February 25, 1998, accepted by the ATCC, and given ATCC Accession Number 209641. A second deposit was made with the ATCC on March 23, 1998, accepted by the ATCC, and given ATCC Accession Number 209691. In accordance with M.P.E.P. § 2410.01 and 37 C.F.R. § 1.808, assurance is hereby given that all restrictions on the availability to the public of ATCC Accession Numbers 209641 and 209691 will be irrevocably removed upon the grant of a patent based on the instant application, except as permitted under 37 C.F.R. § 1.808(b).

In view of the above remarks, Applicants submit that claims 71-114 are fully enabled, and respectfully request that this rejection be reconsidered and withdrawn.

Conclusion

Applicants respectfully request that the above-made remarks be entered and made of record in the file history of the instant application. The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicant would expedite the examination of this application.

If there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136, such an extension is requested and the fee should also be charged to our Deposit Account.

Dated: March 24, 2004

Respectfully submitted,

By _____

Janet M. Martineau
Registration No.: 46,903
HUMAN GENOME SCIENCES, INC.
9410 Key West Avenue
Rockville, Maryland 20850
(301) 315-2723

KKH/JMM/KM/lcc